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To: Interested Parties

From: Elizabeth Childs, M.D.

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Re: Update – FDA ruling on Antidepressant Medication Use in Youth

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The U.S. Food and Drug Administration (FDA) recently ruled to add a "black box" warning to all antidepressant medications currently on the market. This decision, issued on October 15, 2004, was based on a recommendation by the Psychopharmacologic Drugs and Pediatric Advisory Committee (PDPAC), which concluded that there is an increased risk of suicidality in pediatric patients who take certain antidepressant medications when compared to children on placebo.

The "black box" warning is the FDA's strongest safety alert and states that antidepressants may increase the risk of suicide in young patients. "Black box" warnings are directed to prescribing physicians, guiding the doctor to balance the risk of suicidal behavior with clinical need, and to monitor the patient closely for clinical worsening, suicidality, or unusual changes in behavior. The alert also advises families and caregivers of the need for close observation and communication with the doctor. The new warnings will be carried by all antidepressants.

The Department of Mental Health supports the FDA in its efforts to ensure the safety of children, adolescents and adults in how medications are prescribed for treatment of psychiatric conditions, including depression. However, it is important that patients and parents of children who are taking these medications not be unduly alarmed, and that they not simply stop taking their medications without consulting with their physicians. Medications can be an important part of a comprehensive treatment plan for psychiatric disorders. Patients and their physicians should continuously monitor the effect of medications to determine the most appropriate choices in each individual case.

The FDA is also preparing information guides, written specifically for patients and their families and caregivers, to accompany all antidepressant medications regarding the risk of suicidality in children and adolescents. Pharmacists will distribute the information, known as "Medication Guides," with each prescription or refill of a medication.

Families and caregivers with young people taking or considering taking antidepressant medication should be aware of the following list of good practices:

- Monitoring of the patient by physicians, families and caregivers
- Not abruptly stopping medications without medical advice
- Positive and ongoing communication with the prescribing physician
- Careful risk/benefit analysis when considering antidepressants for young people that includes providing information and allowing time for questions and answers from the patient, family and caregivers
- Review of the patient information sheet ("Medication Guide") soon to be developed and available from the FDA , which, when published, will be included with the prescription

For more information on the FDA's action, please refer to its website at:

http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm